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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/996,505
Filing Date: November 28, 2001
Appellant(s): WONG, RAYMOND J.

MAILED

DEC 23 2004

GROUP 1700

Luke Kilyk
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on 11/22/04.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Claimed Subject Matter*

The summary of claimed subject matter contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(8) Prior Art of Record

Appellant's own disclosure of prior art "REDY" cartridge

4,650,587	POLAK et al	03-1987
4,542,015	SMAKMAN et al	09-1985
5,234,603	POTTS	09-1993
3,669,880	MARANTZ et al	06-1972
4,025,608	TAWIL et al	05-1977

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 3-9, 11, 13-16, 19-25, 29-38, and 50-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Appellant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587).

Appellant's disclosure of prior art REDY™ teaches a sorbent cartridge having several layers of sorbents such as zirconium phosphate (ZrP), zirconium hydrous oxide (HZO), activated carbon, etc., (specification pages 5-8 and figure 1 and 8), but does not

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teach sodium zirconium carbonate as one of the layers as in claims 1 and 11. Polak — teaches a sorbent capsule comprising sodium zirconium carbonate (see col 5 line 68 — col 6 line 11) as phosphate ion absorber and/or for elimination of urea. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Polak in the teaching of REDY™ for sorption of urea and phosphate ions because SZC is the state of the art for phosphate ion absorption and/or because of the problems associated with ZrP used by REDY as taught by Polak (see Polak col 3 lines 11-36 and col 6 lines 1-2).

Claims 3 and 13 add the further limitation of ZrP/group IVB metal phosphate, and claims 4 and 13 have ZrP as a layer as taught by REDY.

Claim 5 adds the molecular composition of ZrP, and claim 6 adds the characteristics of ZrP (material property), taught by REDY.

Claims 7 and 8 add limits on residual sulfate and chloride in ZrP (material property). Claim 9, pH of ZrP is a material property.

Claim 14 adds alumina, alumina supported urease, granular activated carbon, or combination thereof, with claim 15 adding these in layers (taught by REDY).

Claim 16 adds the order of the layers as taught by REDY except for the position of the granular activated carbon layer (Appellants admit that it could be in any order on page 21 lines 22-23). *An applicant's expressed recognition of an art-recognized or obvious equivalent may be used to refute an argument that such equivalency does not exist:* In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958). Appellants have not

shown, with evidence, any particular, non-obvious, advantage of changing the position of activated carbon.

Claim 19: The composition of sodium zirconium carbonate by empirical formula is given in col 6 lines 1-9 of Polak, except for the LOD of 30-40%, which is due to water loss. However, water loss from drying sodium zirconium carbonate is an inherent material property. If the composition as claimed by the Appellant is different, that needs to be clearly shown.

Claims 20 and 21: Polak does not specify if the sodium zirconium carbonate satisfies the ANSI/AAMI standard, and the properties listed. However, it would be obvious to one of ordinary skill in the art at the time of invention that the material being the same, it would satisfy such a requirement. Inherency: Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product.

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Whether the rejection is based on inherency' under 35 U.S.C. 102, on-prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Claims 22 adds ZrO and Claim 23 has ZrO in acetate form (taught by REDY).

Claims 29- 31: the quantity of the sodium zirconium carbonate, ZrP, and other components in instant claims is a design/optimization issue depending on the required capacity of the cartridge and the composition of the solution to be treated. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Aller, 42 CCPA 824, 220 F.2d 454, 105 USPQ 233 (1955).

Claim 32 and 36 add immobilized enzyme (Urease in alumina), ion exchange materials (sodium zirconium phosphate), and adsorbent for creatinine (activated carbon), etc, all taught by REDY.

Claim 33 and 37 add chlorine removal material (activated carbon), Claims 34 and 35 add materials in layer form (see fig 1, REDY).

Claim 38 has the added limitation of two or more layers of the absorbents in the cartridge. REDY™ teaches several layers.

Claim 50: Polak in view of REDY™ also teaches an apparatus for conducting dialysis wherein the sorbent cartridge is in fluid communication with a dialyzer.

Claim 51: the dialysis fluid could be spent hemo-dialysis fluid (Polak – abstract)

Claims 52, 54 and 57: The spent fluid could be restored to the original Na⁺ and HCO₃⁻ content (abstract of Polak, and REDY™)

Claim 53: The apparatus could be in blood communication with a patient (see REDY™)

Claim 55 and 56: peritoneal dialysis (See Polak fig, col 5 lines 60-68, and the fig, col 2 lines 25-40 and claim 8 of the incorporated ref).

Claims 58 and 59 add the functional limitation of restoring the levels of sodium and bicarbonate in the dialysate to the fresh dialysate levels [functional limitation: While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).]

Re claims 24 and 25, claim 24 has ratio of ZrO/sodium zirconium carbonate as 1:1 and claim 25 has them blended together. REDY teaches ZrO for removal of phosphate and heavy metals (fig 8 of spec), sodium zirconium carbonate is for the removal of phosphates (Polak). It would be obvious to one of ordinary skill in the art at the time of invention that these two would be put together, since they are for similar functions and one would blend them together, since Polak does not teach any specific the structure of the carbonate in the cartridge. Determining the ratio of the two would be only an optimization based on the capacity needed and the contamination in the solution to be treated [In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Aller, 42 CCPA 824, 220 F.2d 454, 105 USPQ 233 (1955).].

Re claims 60 and 61, the location of the SZC layer is further away from the ZrP layer, which is taught by REDY™ (see fig 1 of spec), since it is already established that the SZC layer is equivalent to the HZO-Ac layer of REDY™.

2. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Appellant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587) as in claim 1 above and further in view of Smakman, et al (US 4,542,015).

Claim 2 adds the limitation, 'one of said layers consisting essentially of sodium zirconium carbonate', REDY™ teaches use of "HZO-Ac" as a separate layer for PO4 absorption (specification page 5). Polak teaches SZC as 'the state of the art' PO4 absorber. It would be obvious to one of ordinary skill in the art at the time of invention to

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the teaching of Polak in the REDY™ cartridge for PO₄ absorption because, Polak teaches that SZC is the state of the art for phosphate ion absorption, and because of the problems associated with HZO as taught by Smakman et al (satisfactory reproducible preparation of HZO is difficult – see col 2 lines 31-37). Also, SZC and HZO-Ac are equivalent and performs the identical function specified in the claim (as taught by Polak) in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification. *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000)

3. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Appellant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587) as in claim 1 above and further in view of Potts (US 5,234,603).

Claims 26-28 adds the further limitations of basic zirconium carbonate, its composition, and purity, respectively, which REDY in view of Polak does not teach. Potts teaches the basic zirconium carbonate (pH 9-14) for removal of heavy metals, transition metals and organic matter from wastewater (col 3 lines 55-61, col 4 lines 19-43), and that zirconium carbonate would hydrolyze to form the polymeric oxide chain (see structure at line 35, col 4 of Potts). It would be obvious to one of ordinary skill in the art at the time of invention to have the teaching of Potts in the teaching of REDY™ in view of Polak for the removal of heavy metal and transition metal ions from the dialysate as taught by Potts.

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4. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Appellant's own disclosure of prior art (REDY™) in view of Polak et al

(US4,650,587) as applied to claim 16 above, and further in view of Marantz et al (US 3,669,880).

Claims 17 and 18 add structural components like filter pads and diffuser. REDY teaches a filter pad (fig 1), but not the diffuser for flow distribution. Marantz teaches a flow distributor and filter pads (see figures 2,3). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Marantz in the teaching of REDY in view of Polak for the flow distribution and for preventing the breaking up and inter-mixing of particles in layers as taught by Marantz (col 2 lines 10-30).

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Appellant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587) as applied to claim 3 above, and further in view of Tawil et al (US 4,025,608).

Claim 3 adds the further limitation of particle size to 30-40 microns for the ZRP particles, which REDY in view of Polak does not teach. Tawil teaches the particle size of ZRP (col 2 lines 54-59). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Tawil in the teaching of REDY in view of Polak for the particle size of ZrO for good flow distribution as taught by Tawil.

(10) Response to Arguments

Appellants' invention is a cartridge for use in cleaning up spent dialysis solutions. There is a similar commercially available cartridge with the trade name REDY, which is described in detail in the appellants' specification. Appellants have also submitted literature on this REDY cartridge in a separate IDS.

Appellants' claims are broad. There are two independent claims, claims 1 and 11. Claim 1 recites a sorbent cartridge having at least two layers, with one of the layers comprising at least sodium zirconium carbonate (SZC). Claim 11, which is broader, recites a sorbent cartridge having an alkali metal – group IVB metal carbonate as a layer.

Claims were rejected under 103(a) as being obvious based on the REDY cartridge (based on the disclosure of known prior art in the specification) in view of Polak. REDY does not teach SZC, but teaches HZO, which is an equivalent of SZC. HZO and SZC are equivalents because they both are for the function of removing PO₄ ions from the dialysate solution by absorption. Polak reference teaches SZC as state-of-the-art for PO₄ absorption, which would motivate one of ordinary skill in the art to use the teaching of Polak in REDY. Polak establishes the equivalency in that it teaches that SZC is the state-of-the-art for PO₄ ion absorption.

Additional references were used for the dependent claims to overcome additional limitations as explained in the rejection above.

Responses to appellant's arguments are given in the same order as presented by the appellants.

In the Arguments Section in pages 6 and 7, Appellants have included a list of groups of claims that stand or fall together. There is a minor problem with these groupings. In the group that contains Claims 3,5-10, 13,30,31 and 58-61, claim 10 is under a different ground for rejection compared to the rest of the claims in that group, and is improperly included in this group. Similarly, in the group containing claims 16-18, claims 17 and 18 are under a different ground for rejection compared to claim 16. However, the claims are correctly grouped under the detailed arguments.

A. Arguments against the rejection of Claims 1, 3-9,11,13-16,19-25,29-38,and 50-61 under 35 U.S.C. 103(a) as being unpatentable over Appellant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587).

a) Patentability of claims 1,11,14,15,20,37,38 and 50-57; rejected under 35 USC 103(a) over appellants own disclosure of prior art "REDY" (henceforth "REDY") in view of Polak:

Claim 1 recites a sorbent cartridge having at least two layers, with one of the layers comprising at least sodium zirconium carbonate (SZC).

The primary ref REDY teaches a cartridge with several layers, but does not teach one of the layers is or as having SZC. The secondary ref Polak teaches SZC as a known state-of-the-art phosphate ion absorber (Polak col 6 lines 1-2). The main thrusts of Appellants' arguments are that Polak does not teach SZC as a layer or teach 'two layers', and that there is no motivation to combine the references. With respect to the

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argument that Polak does not teach SZC as a layer, the rejection does not require that Polak teach SZC as a layer. "Layers" are taught by REDY. Polak teaches SZC. (Polak does teach about layers in the description of the prior arts). Re the motivation, one of ordinary skill in the art would be motivated to use SZC in or as one of the layers in REDY because of its ability to absorb phosphate ions. One of ordinary skill in the art also would use the teaching of Polak in the teaching of REDY for Polak's teaching of "elimination of urea" (see col 6 lines 9-11).

It may also be noted that HZO used by REDY (HZO-Ac, which is the acetate form of HZO) is equivalent in function to SZC because HZO is used as a phosphate absorber in REDY, and the Polak ref teaches that HZO is the state-of-the-art for phosphate absorption, which would give motivation to one of ordinary skill in the art to use SZC in place of HZO.

Appellants' argument that examiner is taking the position that the ZrP from the multi-layered REDY cartridge is replaced with MGP of Polak which includes SZC is not correct. Examiner does not need to take such a position, even though one of ordinary skill in the art could do so. One of ordinary skill in the art could simply add a layer of SZC or MGP+SCZ to the REDY cartridge, or substitute SZC for the HZO-Ac, for the reasons stated above.

Argument that REDY cartridge is on the outside of the patient whereas Polak teaches a capsule for oral consumption is not relevant to the issue because irrespective of the intended use of the Polak capsule, the elimination of urea can be accomplished

by Polak's teaching from a system outside the body, and the teaching of SZC by Polak has nothing to do with the Polak capsule.

Re the argument that how REDY can be combinable with Polak is not seen, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Arguments re claims 14,15,37, and 38 and material properties: material properties do not change just because the appellants decided to put them in a claim. Material properties are inherent in the material.

ANSI/AAMI standard in claim 20 – again, the material property is inherent.

Claim 29: claim 29 recites the amount of SZC in the layer, which one of ordinary skill in the art would be able to optimize depending on the process in which the cartridge is to be employed, and the desired life expectancy of the cartridge for that process. The case law cited is, therefore, applicable. Moreover, the amount of SZC in the layer by itself is not patentable. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if

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such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.). *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art.

b) Patentability of claims 3.5-9,13,30,31 and 58-61; rejected under 35 USC 103(a) over REDY in view of Polak:

Claim 3, on which this group stands together, depends from claim 1 and recites 'the sorbent cartridge further comprising zirconium phosphate' (ZrP).

Appellants argue that Polak discourages the use of ZrP, and teaches MGP as a replacement for ZrP. On the contrary, Polak does not discourage use of ZrP, but teaches MGP as an alternate for ZrP because of the high cost of ZrP. In any case, this argument is not relevant because Polak ref is used as a secondary ref to support the primary ref REDY, and for its teaching of SZC. Nor there is any suggestion in the rejection to blend ZrP and SZC as the Appellants argue. One of ordinary skill in the art could put them as separate layers, and as added layers – not necessarily substitutes.

In response to the argument, "the REDY cartridge would not have any zirconium phosphate layer because it was replaced with the magnesium phosphate product of Polak et al based on the Examiner's reasoning", the rejection has not reasoned that the

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only way one of ordinary skill in the art would combine the references is by this substitution. There can be many different ways of combining the references, such as, add on a layer of SZC or SZC+MGP, or substitute the HZO with SZC. Again, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Rest of the arguments are repetitive.

c) Patentability of claim 4: Again, the argument assumes the replacement of ZrP with MGP. The Polak ref is only a secondary reference and, as stated before, the rejection is not based on its teaching of replacing ZrP with MGP.

d) Patentability of claim 16: Order of arrangement of the layers by itself is not patentable as discussed in the rejection. Appellants do admit in the specification that the order does not make any difference. Appellants have not provided any evidence to show that there is any particular non-obvious advantage to the claimed order of arrangement of the layers. The argument that the present application never mentioned that the REDY cartridge was equivalent to the cartridge of the claimed invention is not relevant because the rejection does not say so. The rejection is based on appellants' own admission that the layers can be arranged in any order. The cited case law states

that applicants' expressed recognition of equivalence can be used to refute the arguments of non-equivalence. A mere reversal or rearrangement of parts (In re Gazda 219 F.2d 449, 104 USPQ 400 (CCPA 1955) or rearrangement of parts (In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) and In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) is unpatentable. Therefore, the order of arrangement in itself is not a reason for patentability, unless appellants can show non-obviousness.

e) Patentability of Claim 19: The Polak ref provides the empirical formula SZC. Appellants' composition includes LOD (water loss). Examiner believes that composition when derived without the LOD will be reduced to the empirical formula given by Polak, which provides sufficient reason for a prima facie case of obviousness. Appellants have not provided any evidence (such as a derivation of the empirical formula without the LOD: it should not be very difficult for the appellants to derive the empirical formula of the SZC without the LOD to show that the composition is different) that this will not be the case.

f) Patentability of Claim 21: the rejection is based on inherency of the material property. Appellants' arguments are not germane to the rejection.

g) Patentability of Claims 22-25: Appellants again assume that examiner suggests substitution of one layer for another in the rejection, which is not true, as explained earlier, and in the rejection. Appellants also do not provide any patentable advantage

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by having both SZC and HZO in the cartridge. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). In this case, both SZC and HZO are taught as PO₄ absorbers by the references Polak and REDY.

h) Patentability of claim 29: This was addressed in the earlier paragraphs, and is repeated. Appellant's arguments are not germane to the issues in claim 29 because Polak is not the primary reference. Irrespective of what the intended purpose of Polak is, it still teaches SZC. Claim 29 has the added limitation of the amount of SZC in the layer of claim 1, which, as addressed in the rejection, can be optimized for the application and the life of the cartridge. The quantity of SZC in the layer alone is not patentable as explained earlier.

i) Patentability of claims 32-36: the arguments are repetitions of the earlier arguments, and were already addressed. No specific arguments presented that address the limitations of these claims.

B. Arguments against the rejection of Claim 2 under 35 U.S.C. 103(a) as being unpatentable over Appellant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587) as in claim 1 above and further in view of Smakman, et al (US 4,542,015).

Claim 2 depends from claim 1 and has the further limitation that the layer consists essentially of SZC.

Appellant's arguments that *consisting essentially of* meant that claim be open only to inclusion of elements that do not materially affect the characteristics of the invention is acknowledged.

Polak teaches that SZC is the state-of-the-art for PO4 ion absorption. Therefore, one of ordinary skill in the art would be motivated to use SZC in the REDY cartridge for this purpose. REDY does have a layer of HZO-Ac, which serves as a PO4 absorber. Therefore, one of ordinary skill would be motivated to provide additional PO4 absorber in the form of the SZC layer, or replace the HZO-Ac with SZC because of the problems associated with HZO, such as the reproducibility of HZO as taught by Smakman (col 2 lines 34-36). [Appellants' argument that Smakman does not teach toxic side effects and rapid deterioration of HZO is true and is acknowledged. However, Smakman does

teach "a satisfactorily reproducible preparation of hydrated zirconium oxide is found to give quite some problems"]

It would also be obvious to one of ordinary skill in the art to have SZC instead of HZO-Ac because they are equivalent in function. There is art-recognized evidence from Polak and REDY that the two are equivalent. *Smith v. Hayashi*, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.). An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

MPEP 2144.07 Art Recognized Suitability for an Intended Purpose:

The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) (Claims to a printing ink comprising a solvent having the vapor pressure characteristics of butyl carbitol so that the ink would not dry at room temperature but would dry quickly upon heating were held invalid over a reference teaching a printing ink made with a different solvent that was nonvolatile at room temperature but highly volatile when heated in view of an article which taught the

desired boiling point and vapor pressure characteristics of a solvent for printing inks and a catalog teaching the boiling point and vapor pressure characteristics of butyl carbitol.

"Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.).

In the present case, Polak recognizes the suitability of SZC as PO₄ absorbent, for the intended purpose of HZO (which is PO₄ absorption) in REDY, and therefore, a prima-facie case of obviousness is established.

Arguments of 'doctrine of equivalents infringement standard' is not relevant because the standard for 'equivalence' should not be different for patentability and infringement; there is no reason why the MPEP would cite such case laws for guidance on equivalence if such standards were different. Re *Kemco Sales* decision, it is understood that this case law is regarding means plus function claims, but it provides the grounds for *establishing* equivalence. Therefore, it is relevant. In the present case, the equivalence is also art-recognized. Therefore, a means plus function recitation is not necessary for an obviousness rejection based on equivalence.

C. Arguments against the rejection of Claims 26-28 under 35 U.S.C. 103(a) as being unpatentable over Appellant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587) as in claim 1 above and further in view of Potts (US 5,234,603).

Claims 26-28 depend from claim 1 and add basic zirconium carbonate, its properties etc. Re the argument that Potts does not suggest removal of urea/ammonia,

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the rejection does not say so. Also, the reason to combine may not be what Appellants intended. The fact that Appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to the argument that zirconium carbonate of Potts **must be** a soluble salt is conjecture on the appellants' part. Properties of basic zirconium carbonate is not going to change whether it is from the appellant or from some other source.

The argument that they are not from the same filed of endeavor is also improper, since the use of the basic zirconium carbonate is described in the Potts reference as a binding agent to precipitate heavy metals from waste water (Potts col 3 line 55 – col 4 line 43). The reference is for cleaning up wastewater, the appellants' claims are for a device for cleaning up used dialysis solution (water-based) which otherwise would be waste, and are therefore at least in the same filed of endeavor if not analogous. Appellants' argument that their filed is removal of urea/ammonia from bodily fluid is incorrect. The device treats used dialysis solutions according to page 1 of the specification.

Rest of the arguments are repetition of earlier arguments.

D. Arguments against the rejection of Claims 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over Appellant's own disclosure of prior art (REDY™) in view of

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Polak et al (US4,650,587) as applied to claim 16 above, and further in view of Marantz et al (US 3,669,880).

Claims 17 and 18 have added limitations of flow distributor and filter pads. The Marantz ref is used for its teaching of distributor and filter pads in a filter cartridge. Appellants arguments directed at the Polak ref as if that ref is being modified is not germane to the issues in the rejection.

E. Arguments against the rejection of Claim 10 under 35 U.S.C. 103(a) as being unpatentable over Appellant's own disclosure of prior art (REDY™) in view of Polak et al (US4,650,587) as applied to claim 3 above, and further in view of Tawil et al (US 4,025,608).

Claim 10 recites the added limitation of particle size of ZrP. Particle size used in the primary ref is not available, and one has to obtain it elsewhere. Tawil teaches this particle size of ZrP, which is used for similar applications. Appellants' arguments directed at the Polak ref, once again, is not germane to the issues.


In conclusion, there are only two differences between the claimed invention and the REDY cartridge: (1) sodium zirconium carbonate (SZC) is used in place of the hydrous zirconium oxide (HZO-Ac) and (2) the positioning of the carbon layer in the cartridge is different. SZC and HZO-Ac are taught by, and are shown as equivalent, by the references. Examiner believes that moving the carbon layer from one end to the other is not patentable.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Patent Examiner

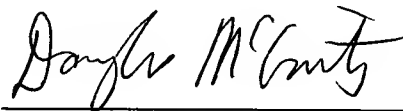
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